

APPLICANTS: Farmer  
U.S.S.N.: 09/369,016

## REMARKS

Claims 51-59, 61-64, and 66-71 are pending. Claim 51 has been amended to require *B. coagulans* and a supplementary lactase enzyme.

No new matter has been added to this application.

### 35 U.S.C. § 103

Claims 51-56, 58-59, 61-64 and 67-70 were rejected for obviousness over Hata in view of Paul and Hansen, in further view of Long and the ATCC Catalogue of Bacteria, and claims 57 and 65-66 were rejected for obviousness over Hata in view of Reid. Applicants traverse these rejections to the extent they apply to the claims as amended herein.

Claim 1 has been amended to require increasing bioavailability of nutrients, e.g., lactose, by administering to a mammal a composition containing two active ingredients, *B. coagulans* and a supplementary lactase enzyme, i.e., lactase in an amount that is supplemental or more than that made by the *B. coagulans* bacteria.

Hata describes the use of *B. coagulans* for making yogurt. Paul generally describes immunoglobulin-containing composition, and also described compositions that optionally contain *L. acidophilus* for treatment of lactose intolerance. Paul also describe compositions optionally containing carbohydrate, lactose. However, Paul fails to describe compositions containing the enzyme lactase administering lactase to mammals. Long describes the use of *B. coagulans* for producing the enzyme lactase. Long describes culturing the cells, treating the cell suspension with toluene, and drying the cell aggregate mass at 50 degrees centigrade to produce the lactase-containing composition, which can be used to hydrolyze lactose. This combination of references fails to describe or suggest using *B. coagulans* and a supplementary lactase for increasing bioavailability of nutrients.

The Examiner further states that “the results presented [by the Fisgus Declaration in Paper No. 23] pertain to ‘lactose intolerance’ and there is no indication that even the specific composition tested is suitable to ‘increase the bioavailability of nutrients in a mammal’.” (See Office Action, page 3). Digestion is the process by which nutrients in ingested food are made bioavailable. Contrary to the Examiner’s statement, the nexus between lactose intolerance and

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bioavailability of nutrients is established in the specification as filed, e.g., at page 12, lines 24-28, of the application, and in the Fiskus Declaration in item 3 (spanning page 1 and 2 of the Declaration). Therefore, the data presented in the Fiskus Declaration indicate that the claimed composition and methods are surprisingly effective in increasing bioavailability of nutrients in ingested food.

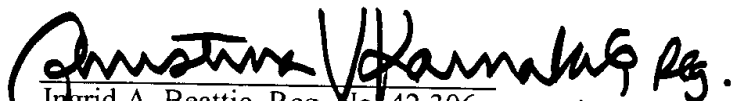
Prior to the invention, there was no teaching or combination of teachings in the art to combine B. coagulans with lactase in an amount supplemental to that produced by the bacteria for the purpose of increasing bioavailability of nutrients in an animal. Moreover, the data in the Fiskus Declaration demonstrate that the combination of the bacteria and exogenous lactase is surprisingly more effective than lactase alone in increasing the bioavailability of nutrients by reducing the symptoms of a syndrome indicative of impaired ability to make nutrients bioavailable, lactose intolerance. For the above-stated reasons, Applicant respectfully asserts that the scope of the Declaration is commensurate with the scope of the pending claims, and that the pending claims are nonobvious in view of the cited references. Applicants request reconsideration and withdrawal of the rejections under §103.

### CONCLUSION

On the basis of the foregoing amendments, Applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact either of the undersigned at the telephone number provided below.

Respectfully submitted,

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